PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 20528.0008.WO	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/US04/31789	International filing date *(day/month/year)* 29 September 2004 (29.09.2004)	Priority date *(day/month/year)* 29 September 2003 (29.09.2003)
International Patent Classification (IPC) or national classification and IPC IPC(7): A61K 38/00, 18, 19; C07K 14/505, 555 and US Cl.: 514/2, 8; 530/351, 397, 399		
Applicant WARREN PHARMACEUTICALS, INC.		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 3 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☐ *(sent to the applicant and to the International Bureau)* a total of ___ sheets, as follows:
      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
28 April 2005 (28.04.2005)	20 July 2005 (20.07.2005)
Name and mailing address of the IPEA/ US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer Regina M. DeBerry Telephone No. (703) 308-0196

Form PCT/IPEA/409 (cover sheet)(January 2004)

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/US04/31789

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This report is based on translations from the original language into the following language _____, which is the language of a translation furnished for the purposes of:

   ☐ international search (under Rules 12.3 and 23.1(b))

   ☐ publication of the international application (under Rule 12.4)

   ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

   ☒ the international application as originally filed/furnished

   ☒ the description:
   pages 1-37 as originally filed/furnished
   pages* NONE received by this Authority on _____
   pages* NONE received by this Authority on _____

   ☒ the claims:
   pages 38-44 as originally filed/furnished
   pages* NONE as amended (together with any statement) under Article 19
   pages* NONE received by this Authority on _____
   pages* NONE received by this Authority on _____

   ☒ the drawings:
   pages 1-9 as originally filed/furnished
   pages* NONE received by this Authority on _____
   pages* NONE received by this Authority on _____

   ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

   ☐ the description, pages _____
   ☐ the claims, Nos. _____
   ☐ the drawings, sheets/figs _____
   ☐ the sequence listing (*specify*): _____
   ☐ any table(s) related to the sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

   ☐ the description, pages _____
   ☐ the claims, Nos. _____
   ☐ the drawings, sheets/figs _____
   ☐ the sequence listing (*specify*): _____
   ☐ any table(s) related to the sequence listing (*specify*): _____

** If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/US04/31789

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 5-9, 15-17, 23-27, 33-35	YES
	Claims 1-4, 10-14, 18-22, 28-32, 36	NO
Inventive Step (IS)	Claims 5-7, 15-17, 23-25, 33-35	YES
	Claims 1-4, 8-14, 18-22, 26-32, 36	NO
Industrial Applicability (IA)	Claims 1-36	YES
	Claims NONE	NO

2. Citations and Explanations (Rule 70.7)
Claims 1-4, 10-14, 18-22, 28-32 and 36 lack novelty under PCT Article 33(2) as being anticipated by Brines et al., US 6,531,121 B2. Brines et al. teach a method for administering a chemically modified or mutant erythropoietin (EPO) for protecting or enhancing EPO responsive cells, tissues, organs and bodily part function (column 3, line 1-column 4, lines 68). Brines et al. teach deglycosylated variants and asialoerythropoietin forms (column 3, lines 18-58). Brines et al. teach the use of non-erythropoietic EPOs (lack EPO effects) (column 5, lines 5-19). Brines et al. teach pharmaceutical compositions comprising chemically modified, mutated, variant EPOs (column 5, line 25-column 6, line 13).

Claims 8, 9, 26 and 27 lack an inventive step under PCT Article 33(3) as being obvious over Brines et al., US 6,531,121 B2 in view of Graddis et al., US 6,291,661 B1. The teachings of Brines et al. are described above. Brines et al. do not teach administering compositions comprising EPO and TNF. Graddis et al. teach the administration of compositions comprising TNF and EPO (column 21, lines 10-19). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of administering chemically modified/mutant forms of EPO for protecting or enhancing EPO responsive cells, tissues, organs and bodily part function as taught by Brines et al. with pharmaceutical compositions comprising EPO and TNF as taught by Graddis et al. with a reasonable expectation of success. The motivation and expected success is provided by Graddis et al. in that Graddis et al. teach that EPO and TNF can be administered together to induce differentiation of hemapoietic cells.

Claims 1-36 meet industrial applicability as defined by PCT Article 33(4) and thus have industrial applicability because the subject matter claimed can be made or used in industry.